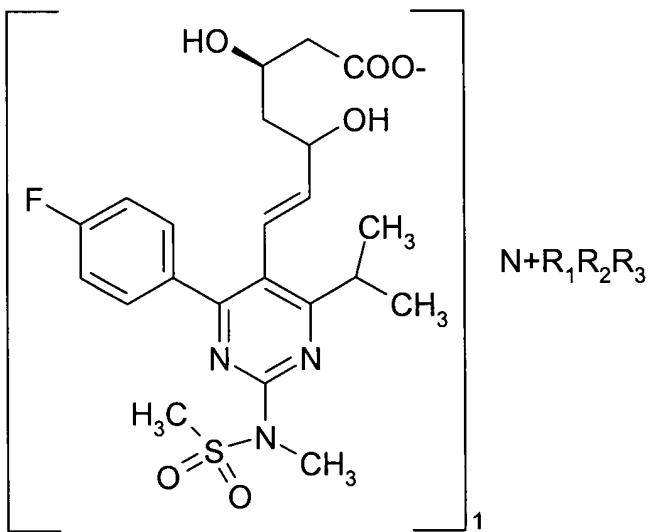


We Claim:

1 1. Amine salts of rosuvastatin of Formula I



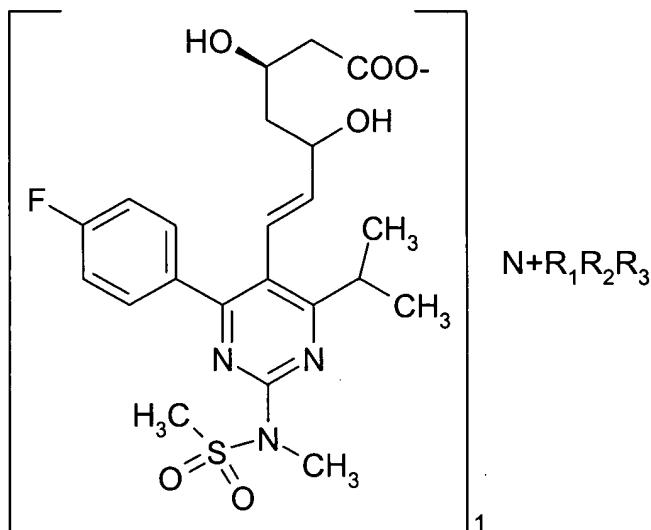
2
3 or solvate, hydrate, crystalline or amorphous form thereof, in which the amine residue has a
4 Formula NR₁R₂R₃ (wherein independently R₁, R₂ and R₃ are H, straight or branched chain C₁-
5 alkyl or hydroxyalkyl, C₃₋₁₀ single or fused ring optionally substituted cycloalkyl,
15 optionally substituted aryl, optionally substituted aralkyl, alkylcycloalkyl, or independently
6 R₁, R₂ and R₃ combine with each other to form a C₃₋₇ membered cycloalkyl ring or
7 heterocyclic residue containing one or more heteroatoms), with the proviso that amine is not
8 ammonia, methylamine, ethylamine, diethanolamine, tri(hydroxymethyl)-methylamine,
9 benzylamine, or 4-methoxybenzylamine.

1 2. The amine salts of rosuvastatin of claim 1, having purity above 99% and
2 diastereomeric impurity less than 0.5%.

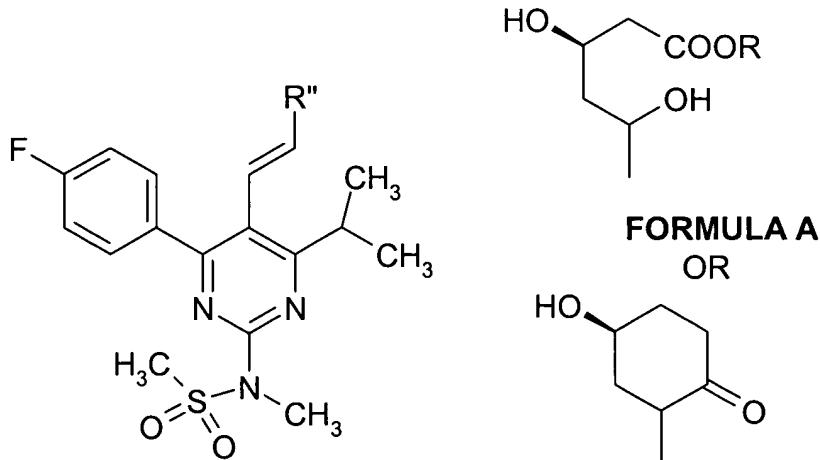
1 3. The compound according to claim 2, wherein the purity is more than 99.5% and
2 diastereomeric impurity less than 0.25%.

1 4. The compound according to claim 3, wherein the purity is more than 99.75% and
2 diastereomeric impurity less than 0.15%.

1 5. A process for the preparation of amine salts of rosuvastatin of Formula I



2
 3 or solvate, hydrate, crystalline or amorphous form thereof, in which the amine residue has a
 4 Formula $NR_1R_2R_3$ (wherein independently R_1 , R_2 and R_3 are H, straight or branched chain C₁-
 5 ₁₅ alkyl or hydroxyalkyl, C₃₋₁₀ single or fused ring optionally substituted cycloalkyl,
 6 optionally substituted aryl, optionally substituted aralkyl, alkylcycloalkyl, or independently
 7 R_1 , R_2 and R_3 combine with each other to form a C₃₋₇ membered cycloalkyl ring or
 8 heterocyclic residue containing one or more heteroatoms), with the proviso that amine is not
 9 ammonia, methylamine, ethylamine, diethanolamine, tri(hydroxymethyl)-methylamine,
 10 benzylamine, or 4-methoxybenzylamine,
 11 the process comprising:
 12 a) treating rosuvastatin of Formula II

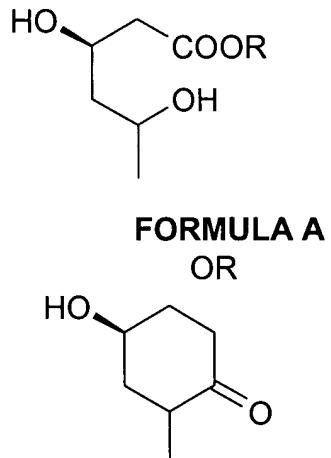
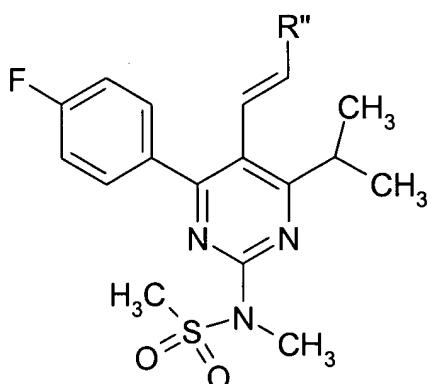


14 with an amine of Formula $\text{NR}_1\text{R}_2\text{R}_3$ (wherein independently R_1 , R_2 and R_3 are H,
15 straight or branched chain C_{1-15} alkyl or hydroxyalkyl, C_{3-10} single or fused ring
16 optionally substituted cycloalkyl, optionally substituted aryl, optionally substituted
17 aralkyl, alkylcycloalkyl, or independently R_1 , R_2 and R_3 combine with each other to
18 form a C_{3-7} membered cycloalkyl ring or heterocyclic residue containing one or more
19 heteroatoms), with a proviso that the amine is not selected from ammonia,
20 methylamine, ethylamine, diethanolamine, tri(hydroxymethyl)-methylamine,
21 benzylamine, or 4-methoxybenzylamine; and

22 b) isolating the amine salt of rosuvastatin of Formula I.

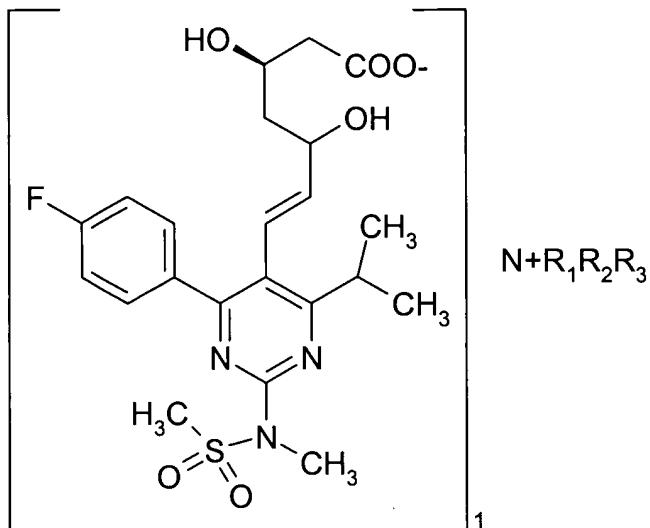
1 6. (Cancelled)

1 7. A process for preparation of amorphous or crystalline rosuvastatin calcium of Formula
2 IIa from amine salt of Formula I,



3
4 **FORMULA B**

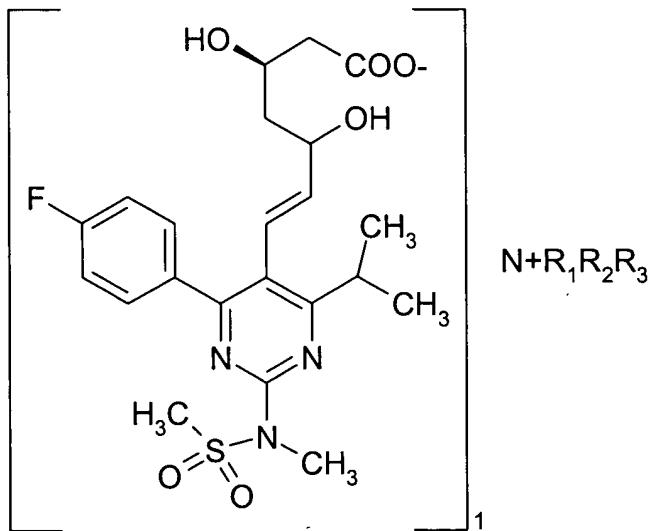
3
4 wherein the process comprises of
5 a) treating an amine salt of Formula I,



6

7 or solvate, hydrate, crystalline or amorphous form thereof, in which the amine residue has
 8 a Formula NR₁R₂R₃ (wherein independently R₁, R₂ and R₃ are H, straight or branched
 9 chain C₁₋₁₅ alkyl or hydroxyalkyl, C₃₋₁₀ single or fused ring optionally substituted
 10 cycloalkyl, optionally substituted aryl, optionally substituted aralkyl, alkylcycloalkyl, or
 11 independently R₁, R₂ and R₃ combine with each other to form a C₃₋₇ membered cycloalkyl
 12 ring or heterocyclic residue containing one or more heteroatoms), with a proviso that the
 13 amine is not selected from ammonia, methylamine, ethylamine, diethanolamine,
 14 tri(hydroxymethyl)-methylamine, benzylamine, or 4-methoxybenzylamine, with an acid;
 15 b) optionally isolating rosuvastatin acid or a lactone thereof;
 16 c) adding a base and calcium ions;
 17 d) isolating amorphous rosuvastatin calcium; and
 18 e) optionally converting amorphous rosuvastatin calcium to crystalline rosuvastatin
 19 calcium.

1 8. A process for the preparation of amorphous rosuvastatin calcium from amine salt
 2 rosuvastatin of Formula I



3

4 or solvate, hydrate, crystalline or amorphous form thereof, in which the amine residue has a
 5 Formula NR₁R₂R₃ (wherein independently R₁, R₂ and R₃ are H, straight or branched chain C₁.
 6 alkyl or hydroxyalkyl, C₃₋₁₀ single or fused ring optionally substituted cycloalkyl,
 7 optionally substituted aryl, optionally substituted aralkyl, alkylcycloalkyl, or independently
 8 R₁, R₂ and R₃ combine with each other to form a C₃₋₇ membered cycloalkyl ring or
 9 heterocyclic residue containing one or more heteroatoms), with a proviso that the amine is not
 10 selected from ammonia, methylamine, ethylamine, diethanolamine, tri(hydroxymethyl)-
 11 methylamine, benzylamine, or 4-methoxybenzylamine,

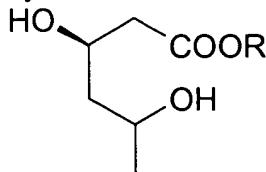
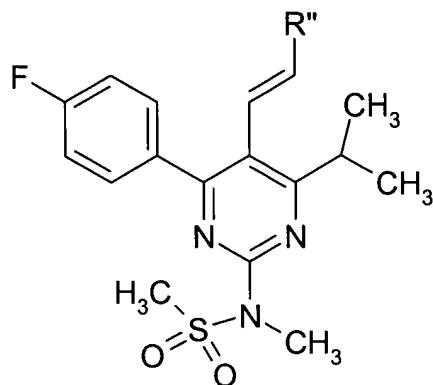
12 the process comprising

13 a) treating an amine salt of rosuvastatin with a base and a calcium ions; and

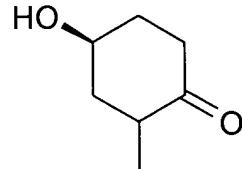
14 b) isolating the amorphous rosuvastatin calcium from the reaction mass.

1 9. Amorphous rosuvastatin calcium prepared by a process according to claims 7 and 8
 2 having a purity of at least above 99% having less than 0.5% of diastereomeric impurity.

1 10. A process for preparation of amorphous or crystalline rosuvastatin magnesium of



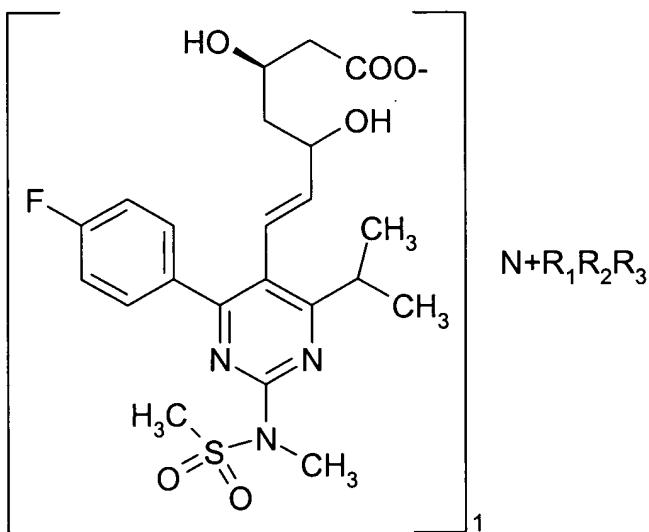
FORMULA A
OR



FORMULA B

2 Formula IIb

3 from amine salt of Formula I,



4

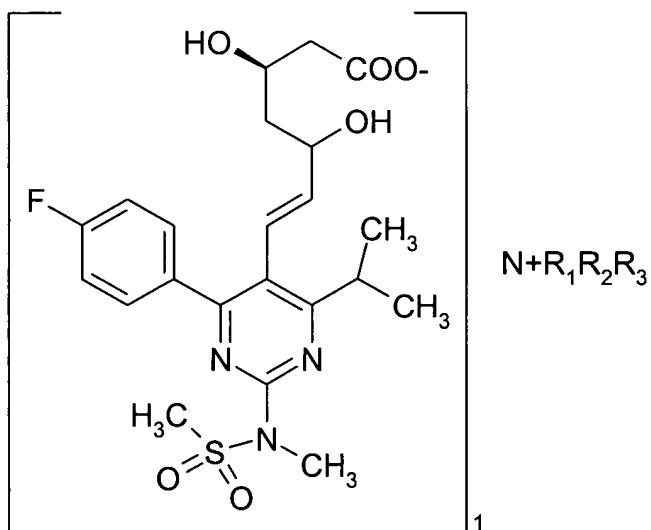
5 or solvate, hydrate, crystalline or amorphous form thereof, in which the amine residue has a
6 Formula NR₁R₂R₃ (wherein independently R₁, R₂ and R₃ are H, straight or branched chain C₁-
7 15 alkyl or hydroxyalkyl, C₃₋₁₀ single or fused ring optionally substituted cycloalkyl,
8 optionally substituted aryl, optionally substituted aralkyl, alkylcycloalkyl, or independently
9 R₁, R₂ and R₃ combine with each other to form a C₃₋₇ membered cycloalkyl ring or
10 heterocyclic residue containing one or more heteroatoms), with a proviso that the amine is not
11 selected from ammonia, methylamine, ethylamine, diethanolamine, tri(hydroxymethyl)-
12 methylamine, benzylamine, or 4-methoxybenzylamine,

13 wherein the process comprises:

- 14 a) treating an amine salt of Formula I with an acid;
- 15 b) optionally isolating rosuvastatin acid or a lactone thereof;
- 16 c) adding a base and magnesium ions;
- 17 d) isolating crystalline rosuvastatin magnesium; and
- 18 e) optionally converting crystalline rosuvastatin magnesium to amorphous rosuvastatin
- 19 magnesium.

1 11. A process according to claim 10 wherein the acid is selected from inorganic mineral
2 acids or organic acids.

1 12. A process for the preparation of amorphous rosuvastatin magnesium from amine salt
2 of rosuvastatin of Formula I



3 or solvate, hydrate, crystalline or amorphous form thereof, in which the amine residue has a
4 Formula NR₁R₂R₃ (wherein independently R₁, R₂ and R₃ are H, straight or branched chain C₁₋₁₅
5 alkyl or hydroxyalkyl, C₃₋₁₀ single or fused ring optionally substituted cycloalkyl,
6 optionally substituted aryl, optionally substituted aralkyl, alkylcycloalkyl, or independently
7 R₁, R₂ and R₃ combine with each other to form a C₃₋₇ membered cycloalkyl ring or
8 heterocyclic residue containing one or more heteroatoms), with a proviso that the amine is not

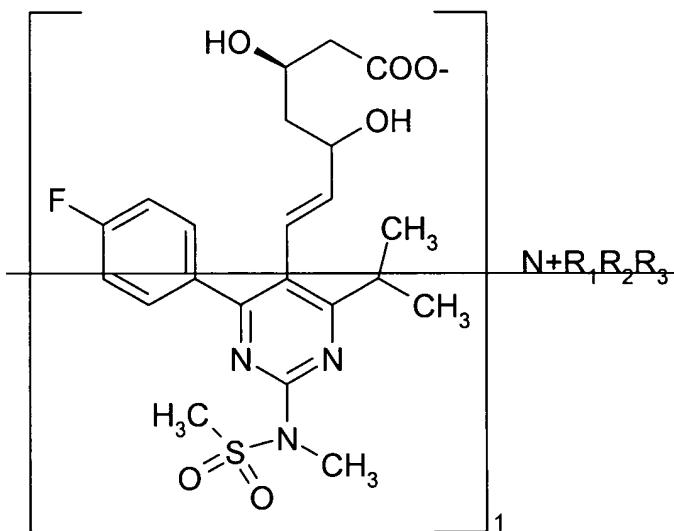
10 selected from ammonia, methylamine, ethylamine, diethanolamine, tri(hydroxymethyl)-
11 methylamine, benzylamine, or 4-methoxybenzylamine,
12 which comprises:

- 13 a) treating an amine salt of rosuvastatin with a base and a magnesium ions; and
14 b) isolating the crystalline rosuvastatin magnesium from the reaction mass.

1 13. Highly pure rosuvastatin calcium or rosuvastatin magnesium in crystalline or
2 amorphous form thereof having purity of at least above 99.5% and diastereomeric impurity
3 less than 0.25%.

1 14. – 23. (Cancelled)

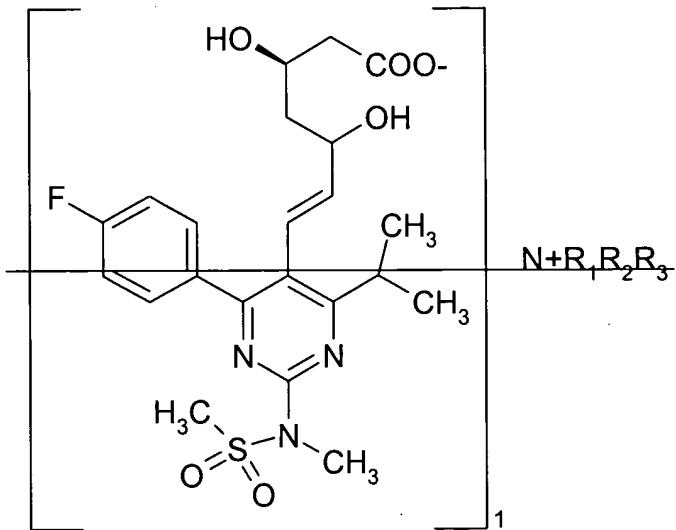
1 24. (Currently Amended) A pharmaceutical composition comprising amine salts of
2 rosuvastatin of Formula I according to claim 1.



3 or solvate, hydrate, crystalline or amorphous form thereof, in which the amine residue has a
4 Formula NR₁R₂R₃ (wherein independently R₁, R₂ and R₃ are H, straight or branched chain C₁-
5 alkyl or hydroxyalkyl, C₃-10 single or fused ring optionally substituted cycloalkyl,
6 optionally substituted aryl, optionally substituted aralkyl, alkylcycloalkyl, or independently
7 R₁, R₂ and R₃ combine with each other to form a C₃-7 membered cycloalkyl ring or
8 heterocyclic residue containing one or more heteroatoms), with a proviso that the amine is not
9 selected from ammonia, methylamine, ethylamine, diethanolamine, tri(hydroxymethyl)-

11 methylamine, benzylamine, or 4-methoxybenzylamine, with a pharmaceutically acceptable
12 diluent or carrier.

1 25. (Currently Amended) A method of treating disease conditions wherein HMG-CoA is
2 implicated, which comprises of administering to a mammal in need thereof a therapeutically
3 effective amount of amine salt of rosuvastatin of Formula I according to claim 1.



4 or solvate, hydrate, crystalline or amorphous form thereof, in which the amine residue has a
5 ~~Formula NR₁R₂R₃ (wherein independently R₁, R₂ and R₃ are H, straight or branched chain C₁-~~
6 ~~C₁₅-alkyl or hydroxyalkyl, C₃₋₁₀ single or fused ring optionally substituted cycloalkyl,~~
7 ~~optionally substituted aryl, optionally substituted aralkyl, alkylcycloalkyl, or independently~~
8 ~~R₁, R₂ and R₃ combine with each other to form a C₃₋₇ membered cycloalkyl ring or~~
9 ~~heterocyclic residue containing one or more heteroatoms), with a proviso that the amine is not~~
10 ~~selected from ammonia, methylamine, ethylamine, diethanolamine,~~
11